Translation

PCT/FR2003/003124

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B1364WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR2003/003124	International filing date (*day/month/year*) 21 octobre 2003 (21.10.2003)	Priority date (*day/month/year*) 21 octobre 2002 (21.10.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/444, 31/4164, 31/341, 31/426, A61P 1/04		
Applicant SIDEM PHARMA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03 mai 2004 (03.05.2004)	09 December 2004 (09.12.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/003124

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-9, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages 1-9, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR 03/03124

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following document:

D1: UCHIYAMA ET AL.: "The long lasting effect of TU-199 a novel H+,K+-ATPase inhibitor on gastric secretion in dogs" J.PHARM. PHARMACOL., vol. 51, 1999, pages 457-464, XP008018962

1. The subject matter of the claims relates to the first medical use of a composition including tenatoprazole and a histamine H2-receptor antagonist, and the use thereof for treating gastric hyperacidity.

Said subject matter is novel over the available prior art (PCT Article 33(2)).

2. D1 describes tenatoprazole (proton pump inhibitor: PPI) as being a gastric antacid, the half-life of which is greater than that of omeprazole and lansoprazole (page 463, left-hand column).
The difference between the known use of tenatoprazole as a gastric antacid and the subject matter of the present application lies in the addition of a histamine H2-receptor antagonist thereto.

The present description (page 3) states that the effect obtained by this combination is greater than that obtained by each of the compounds used individually.

In the light of the prior art, the problem to be solved is therefore that of producing a drug including tenatoprazole for treating gastric hyperacidity that is more effective than tenatoprazole alone.

The solution proposed by the application consists in adding a histamine H2-receptor antagonist (anti-H2), known for the same treatment, to the tenatoprazole.

However, given that the prior art demonstrates (cf. page 3) that the combination of omeprazole+ranitidine (different PPI + anti-H2) is not superior to omeprazole alone, a person skilled in the art would not have attempted to reproduce a PPI + anti-H2 combination using tenatoprazole as the PPI.

Consequently, the subject matter of claims 1 to 8 meets the requirements of inventive step (PCT Article 33(3)).